K083830

Section 5

MAR 20 2009

510(k) Summary

Contents

K 083830

510(k) Summary

OSCAR Bone Resector

Common Name:	Ultrasonic Surgical Instrument
Classification Name:	Instrument, Surgical, Sonic And Accessory/Attachment
Product Code:	JDX
Sponsor:	Orthosonics Ltd Bremridge House Ashburton Devon TQ13 7JX UK T: +44 1364 652426 F: +44 1364 653589
Contact:	Dr. Michael J.R. Young,

A. REASON FOR SUBMISSION

This 510(k) is being filed to obtain clearance to market the OSCAR Bone Resector.

B. LEGALLY MARKETED PREDICATE DEVICES

This premarket notification will demonstrate that the OSCAR Bone Resector is substantially equivalent to the Orthosonics OSCAR OE3000DB cleared by FDA as K051053, Hall Versipower Surgical Instrument System (K895198) and the Biomet Orthopedics Inc Ultra-Drive 3 (K031280).

C. DEVICE DESCRIPTION

The OSCAR Bone Resector consists of a power module which generates the ultrasonic energy and provides overall control of the device, a reusable handpiece and a range of single use cutting blades. OSCAR Bone Resector employs longitudinal mode ultrasound in conjunction with a low frequency reciprocating motion to cut and remove bone.

D. INTENDED USE

The Orthosonics OSCAR Bone Resector is intended to be used for cutting and removal of bone in orthopedic applications.

E. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the OSCAR Bone Resector are the same as those of the predicate devices. Both OSCAR Bone Resector and Orthosonics OSCAR OE3000DB systems are designed to use ultrasound to cut bone during orthopedic surgery. The main difference is that the OSCAR Bone Resector system also incorporates a low frequency reciprocating action, similar to the Hall Versipower Plus Oscillator saw, making the cut quicker, more controllable and cooler than either predicate device, and particulary reducing the likelihood of soft tissue collateral damage.

F. SUBSTANTIAL EQUIVALENCE SUMMARY

OSCAR Bone Resector is a medical device, that uses ultrasound to cut bone. This is the same function as embraced by the predicate device.

OSCAR Bone Resector has the same technological characteristics as the predicate devices. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, performance testing was carried out for some characteristics. The data from this testing are available and are presented in this 510(k). The data do in fact demonstrate equivalence.

G. TESTING

Testing to FCC Part 18 will be carried out prior to marketing the device in the USA. Electrical testing to UL 60601-1 will be carried out by Underwriters Laboratories before marketing the device in the USA.

H. CONCLUSIONS

This premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthosonics, Ltd.
% Michael J.R. Young, Ph.D.
Managing Director
Bremridge House
Ashburton, Devon TQ13 7JX
United Kingdom

MAR 20 2009

Re: K083830
Trade/Device Name: OSCAR Bone Resector
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachment
Regulatory Class: II
Product Code: JDX
Dated: December 18, 2008
Received: December 23, 2008

Dear Dr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

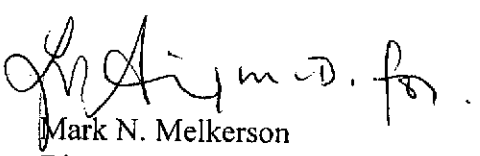
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 083830

Device Name: OSCAR Bone Resector

Indications For Use:

The Orthosonics OSCAR Bone Resector is intended to be used for cutting and removal of bone in orthopedic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083830